U.S. Application No. 09/522,716 Filed: March 10, 2000

### **REMARKS**

### I. Preliminary Remarks

With this response, Applicant amends claims 26 and 47 by clarifying that antigen-presenting cells used in the methods of the instant invention are antigen-presenting cells selected from the group consisting of professional antigen-presenting cells and facultative antigen-presenting cells. The written support for this amendment can be found throughout the instant specification as filed, for example, at page 18.

Applicant also amends claim 47 to clarify that the claim is directed to a method of inhibiting tumor cell growth. The support for this amendment can be found throughout the instant specification as filed, for example, at pages 50 to 53.

### II. Patentability Arguments

## A. The Rejection of Claims 47-53 Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn.

In the advisory action, the Examiner maintained rejection of claims 47-53 under 35 U.S.C. § 112, first paragraph, allegedly because the claims when interpreted broadly read on the prevention of a tumor. Claim 47 is amended with this response to recite a limitation to a method of inhibiting tumor cell growth. The amendment is fully supported by the specification as filed. For example, Example 6 (pages 50 to 53) provides that onset of tumors was delayed in animals injected with antigen-presenting cells of the instant invention and therefore, the growth of tumor cells was inhibited in the animals.

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In conclusion, rejection of claims 47-53 under 35 U.S.C. § 112, first paragraph, may be properly withdrawn because claim limitation to a method of inhibiting tumor cell growth is fully supported by the specification as filed.

# B. The Rejections of Claims 26, 41-46 and 54 Under 35 U.S.C. §§ 102(b) and 102(e) Should be Withdrawn.

The Examiner alleges that the term "antigen-presenting cells" as recited in claim 26 may include tumor cells taught by Eisenbach *et al.* in EP 0569678 A2 (Eisenbach EP) and in U.S. Patent No. 5,750,102 (Eisenbach US). In response, Applicant asserts that antigen-presenting cells recited in amended claim 26 do not include tumor cells and even if they did, they would still be distinguishable from those of Eisebach.

Claim 26 is presently amended to recite "wherein said antigen-presenting cell is selected from the group consisting of professional antigen-presenting cells and facultative antigen-presenting cells." The amendment to claim 26 is fully supported by the specification as filed, for example, at page 18, wherein Applicant writes "the antigen presenting cells may comprise those cells which are known as professional or constitutive antigen-presenting cells such as macrophages, dendritic cells and B cells. . . monocytes, macrophages, marginal zone Kupffer cells, microglia, Langerhans' cells, interdigitating dendritic cells, follicular dendritic cells, and T cells. . . [as well as] facultative antigen-presenting cells [such as] astrocytes, follicular cells, endothelium and fibroblasts." In summary, the list of cells that Applicant proposes to use as antigen-presenting cells does not include tumor cells, while the cells disclosed by Eisenbach are tumor cells.

In the second full paragraph of page 23, Applicant writes "The semi-allogeneic immunogenic cells of the present invention may also be genetically selected by fusing an antigen-presenting cell

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with a tumor cell." Thus, when Applicant uses tumor cells in its description, Applicant refers to the cells by the term "tumor cells" to distinguish the cells from non-tumor antigen-presenting cells.

In summary, amended claim 26 recites antigen-presenting cells that are not tumor cells and because the cells described by Eisenbach are tumor cells, Eisenbach cannot anticipate the present invention.

The Examiner also alleges in the Advisory action that "the manipulation of the cell to incorporate total genomic DNA and MHC molecules as claimed do not distinguish the claimed cell from that of Eisenbach tumor cell." Applicant respectfully disagrees because Eisenbach tumor cells are genotypically different from antigen-presenting cells of the instant invention in at least the following aspects.

To prepare cells for its methods, Eisenbach transfects tumor cells of a patient with cloned MHC which is allogeneic to the patient (abstracts of Eisenbach EP and of Eisenbach US). Thus, genome of Eisenbach cells consists of the patient's chromosomes and an allogeneic MHC-encoding sequence in the form of a cDNA. In contrast, Applicant does not transfect patient's cells, but rather transfects antigen-presenting cells of a donor with the sheared total genomic DNA from the patient's tumor. Therefore, genome of the presently claimed cells consists of chromosomes of the antigen-presenting cells and portions of the tumor cell genome and not just a single cDNA and the genome of the recipient tumor cell.

Further, even if antigen-presenting cells of the instant invention were tumor cells, the cells would be different from the Eisenbach cells because such tumor cells would contain their own genomic DNA and additional genomic DNA from tumor cells that was used to transfect the cells and not just its native tumor genomic DNA and an additional cDNA encoding the appropriate MHC provided by transfer.

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Finally, even if antigen-presenting cells of the instant invention were tumor cells and were transformed with genomic DNA of other tumor cells with the same genotype, then still such cells would be different from Eisenbach cells because the former cells would have different genetic make up in as much as they would contain their own genomic DNA and also additional genomic DNA of the second cells that were used to transform the first ones.

In conclusion, because Eisenbach references do not teach an antigen-presenting cell transfected with total genomic DNA from a tumor, as defined in the present application, the Eisenbach references cannot anticipate claim 26 as the matter of law. For the reasons stated above, rejection of claims 26, 41-46 and 54 under 35 U.S.C. §§ 102(b) and 102(e) over Eisenbach US and Eisenbach EP may be properly withdrawn.

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#### Conclusion

Applicant respectfully submits that claims, as currently amended, are in condition for allowance and early notification thereof is requested. If in the interest of expediting prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

Respectfully submitted,

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